

**REMARKS/ARGUMENTS**

Upon entry of the present amendment, claims 1, 2, 6, 9, 11, 12, 15, 18, 19, 21, 22, 25, 28, 30-34, 36, 37, 40, 43, 45-48, 51, 54, 180, and 182-186 are pending in this application.

Claims 3-5, 7, 8, 10, 13, 14, 16, 17, 20, 23, 24, 29, 35, 38, 39, 41, 42, 44, 49, 50, 52, 53, 55-80, 83-122, 125-179, 181 and 187-203 have been cancelled. Applicants reserve the right to prosecute these claims in a subsequent application(s).

Claims 1, 6, 9, 11, 12, 15, 21, 25, 31, 40, 43, 45, 51, 180 and 182 have been amended and claims 204-209 have been added.

The present amendment does not introduce new matter.

**Restriction Requirement**

Applicants acknowledge with appreciation that the Examiner has added claims 31-44 and 145-152 as part of Group I. Applicants also acknowledge with appreciation that claims 45-54 have been examined as part of Group I.

**Species Election Requirement**

Applicants acknowledge with appreciation that the Examiner has examined the claims based on the Applicants election of an aqueous solution.

**Allowable Subject Matter**

Applicants acknowledge with appreciation that the Examiner has stated that claims 5, 6, 39, 40, 50, 51 and 182 would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. §112 and that claims 14, 15, 24 and 25 would be allowable if rewritten to overcome the rejections under 35 U.S.C. §112, second paragraph (*See, Office Action at page 8*).

Applicants also acknowledge with appreciation that the Examiner has stated that the prior art of record does not suggest, teach or disclose solubilizing β-lapachones with a beta-cyclodextrin (*See, Office Action at page 8*).

**Rejection under 35 U.S.C. §112, First Paragraph**

Claims 1-3, 9, 11, 12, 18, 19, 21, 22, 28, 30-37, 43, 45-48, 180, 181 and 183-187 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for

compositions comprising  $\beta$ -lapachones and certain particular solubilizing agents, e.g. claim 4, does not reasonably provide enablement for combinations of  $\beta$ -lapachones and other solubilizing agents generally. The Examiner states that the specification does not enable any person skilled in the art to which it pertains, or with which is most nearly connected, to practice the invention commensurate in scope with these claims (*See, Office Action at pages 3-6*). More specifically, the Examiner states that the specification provides no direction or guidance for  $\beta$ -lapachones and any solubilizing agent, as only a limited number of combinations are exemplified in the working examples (*See, Office Action at page 5*). Applicants traverse. However, in order to advance prosecution Applicants have cancelled claims 3, 35 and 181 and thus the rejection is moot as it applies to these claims. Applicants reserve the right to prosecute these claims in a subsequent application(s). Applicants respectfully traverse this rejection with respect to pending claims 1, 2, 9, 11, 12, 18, 19, 21, 22, 28, 30-34, 36-37, 43, 45-48, 180 and 183-187 as amended herein and claims 204-209 added herein.

Although Applicants submit that the instant application is enabled for any pharmaceutically acceptable solubilizing carrier molecule, to facilitate prosecution independent claim 1, from which 2 and 9 depend; independent claim 11, from which 12, 18 and 19 depend; independent claim 21, from which 22, 28 and 30 depend; independent claim 31, from which 32-34, 36-37 and 43 depend; independent claim 45, from which 46-48 depend; and independent claim 180 from which 183-187 depend, have been amended to recite "...a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin".

As amended, claims 1, 11, 21, 31, 45 and 180 recite a specific solubilizing carrier molecule, beta-cyclodextrin, which the Examiner has indicated is allowable subject matter and is free of the prior art (*See, Office Action at page 8*). In view of the above, Applicant's respectfully submit that pending claims 1, 2, 9, 11, 12, 18, 19, 21, 22, 28, 30-34, 36-37, 43, 45-48, 180 and 183-187, as amended herein, and claims 204-209, added herein, are enabled for compositions or kits comprising  $\beta$ -lapachone or analogs and derivatives thereof and a pharmaceutically acceptable solubilizing carrier molecule which is beta-cyclodextrin and that one of ordinary skill in the art would be able to practice the invention commensurate in scope with the claims as amended herein. Therefore, Applicants respectfully request that the present rejection be withdrawn.

**Rejection under 35 U.S.C. §112, Second Paragraph**

Claims 11-25 and 28-30 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner states that the term “substantially” in claims 1 and 21 is a relative term which renders the claim indefinite (*See, Office Action at page 6*). Applicants traverse. However, in order to advance prosecution Applicants have cancelled claims 13, 14, 16, 17, 20, 23, 24 and 29 and thus the rejection is moot as it applies to these claims. Applicants have amended independent claim 11, from which 12, 18 and 19 depend, and independent claim 21, from which 22, 28 and 30 depend, to delete the term “substantially”.

In view of the above, Applicant’s respectfully submit that pending claims 11, 12, 15, 18, 19, 21, 22, 25, 28, and 30, as amended herein, are definite and that one of ordinary skill in the art would be reasonably apprised of the scope of the invention. Therefore, Applicants respectfully request that the present rejection be withdrawn.

**Rejection under 35 U.S.C. §102(a)**

Claims 1-4, 9, 21-23, 28, 30-38, 43, 45-49, 180, 181 and 183-187 are rejected under 35 U.S.C. §102(a), as being anticipated by Pardee et al. (WO 00/61142) (*See, Office Action at pages 7-8*). Applicants have cancelled claims 3, 4, 23, 35, 38, 49, 181 and 187 and thus the rejection is moot as it applies to these claims. Applicants reserve the right to prosecute these claims in a subsequent application(s). Applicants respectfully traverse this rejection with respect to pending claims 1, 2, 9, 21, 22, 28, 30-34, 36-37, 43, 45-48, 180 and 183-187 as amended herein and claims 204-209 added herein.

As discussed *supra*, although Applicants disagree with the present rejection over Pardee *et al.*, to facilitate prosecution, Applicants have amended independent claims 1, 21, 31, 45, and 180 to recite “...a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin” as suggested by the Examiner and to which the Examiner has stated is free of the prior art of record (*See, Office Action at page 8*). Therefore, Applicants respectfully request that the present rejection be withdrawn.

CONCLUSION

In view of the aforementioned remarks and amendments, the Applicants believe that each of pending claims is in condition for allowance. Reconsideration, withdrawal of the rejections, and passage of the case to issue is respectfully requested. A notice to this effect is earnestly solicited.

If, upon receipt and review of this amendment, the Examiner believes that the present application is not in condition for allowance and that changes can be suggested which would place the claims in allowable form, the Examiner is respectfully requested to call Applicant's undersigned counsel at the number provided below.

Respectfully submitted,

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